Aprea Therapeutics Announces Early Clinical Proof-Of-Concept in the Ongoing ACESOT-1051 Dose-Escalation Trial Evaluating WEE1 Inhibitor APR-1051, Including Partial Response Observed on First Scan

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- Approximately 50% reduction in target lesion and greater than 90% decrease in CA-125 observed in endometrial cancer patient
- The unconfirmed partial response (uPR) that was observed in the first scan has been achieved at the 150 mg dose, with 220 mg cohort currently enrolling in the ACESOT-1051
- Potential dose-response trend observed with increasing single-agent activity across the 70 mg, 100 mg, and 150 mg cohorts
- Data provide early clinical proof-of-concept for single-agent APR-1051 in patients with advanced solid tumors

DOYLESTOWN, Pa., Jan. 29, 2026 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) (“Aprea” or the “Company”), a clinical-stage biopharmaceutical company developing innovative therapies that exploit cancer-specific vulnerabilities while minimizing damage to healthy cells, today announced the first unconfirmed partial response (uPR) observed in a patient enrolled in its ongoing Phase 1 ACESOT-1051 dose-escalation study (A Multi-Center Evaluation of WEE1 Inhibitor APR-1051 in Patients with Advanced Solid Tumors).

This early clinical activity was observed in a patient with PPP2R1A-mutated uterine serous carcinoma, a form of endometrial cancer, treated at the 150 mg dose level of APR-1051, with dose escalation continuing into higher dose cohorts to establish the recommended Phase 2 dose (RP2D). At the protocol-defined 8-week imaging assessment, the patient achieved a 50% reduction in target lesion size per RECIST v1.1 criteria, along with a marked reduction in cancer antigen 125 (CA-125) levels, from 732 to 70 U/mL, a well-recognized tumor marker in endometrial cancer.

In earlier cohorts of ACESOT-1051 study, multiple patients achieved stable disease with reductions in tumor burden, including a 5% reduction at the 70 mg dose in a patient with HPV-positive head and neck squamous cell carcinoma (HNSCC) and a 15% reduction in a patient with FBXW7-mutated colon cancer treated at the 100 mg dose. This patient has remained on therapy for over 210 days and is approaching their eighth treatment cycle. In addition, a second patient treated at the 150 mg dose level achieved stable disease at the first follow-up imaging assessment.

Collectively, these findings suggest that APR-1051 may have therapeutic potential across a range of solid tumors. Enrollment in the 220 mg dose level cohort of the study is currently underway, and the company intends to increase enrollment of HPV-positive patients in the ongoing trial.

“These early single-agent data demonstrate that APR-1051 has clinical activity as a single agent,” said Anthony Tolcher, MD, FRCPC, Principal Investigator at Next Oncology. “The observation of a partial response on the first scan, together with a decrease in tumor marker at this dose level, supports continued clinical evaluation of APR-1051.”

Oren Gilad, PhD, Chief Executive Officer of Aprea Therapeutics, added, “These preliminary results provide early proof-of-concept for single-agent activity of APR-1051 and support our strategy of targeting cancers with specific genomic alterations, including HPV-positive disease and PPP2R1A, FBXW7, CCNE1, TP53 and KRAS mutations. The potential dose-response trend and favorable safety profile observed in the ongoing dose-escalation study reinforce our confidence in the potential of APR-1051 as a differentiated WEE1 inhibitor for patients with advanced solid tumors. We look forward to providing additional updates in the first half of 2026 and completing dose escalation later in the year.”

About the ACESOT-1051 Trial

ACESOT-1051 is a first-in-human, open-label Phase 1 study evaluating the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of single-agent APR-1051 in patients with advanced solid tumors harboring cancer-associated genetic alterations. The dose-escalation portion of the study is expected to enroll up to 50 patients across nine planned dose cohorts, ranging from10 mg to 300 mg administered once daily. APR-1051 is administered orally once daily in continuous 28-day cycles. To date, enrollment has evaluated doses up to 150 mg, with the 220 mg cohort currently enrolling. For more information, refer to ClinicalTrials.gov ID NCT06260514.

About Aprea
Aprea is pioneering a new approach to treat cancer by exploiting vulnerabilities associated with cancer cell mutations. This approach was developed to kill tumors but to minimize the effect on normal, healthy cells, decreasing the risk of toxicity that is

frequently associated with chemotherapy and other treatments. Aprea's technology has potential applications across multiple cancer types, enabling it to target a range of tumors, including ovarian, endometrial, colorectal, prostate, and breast cancers.

The company's lead programs are APR-1051, an oral, small-molecule inhibitor of WEE1 kinase, and ATRN-119, a small molecule ATR inhibitor, both in clinical development for solid tumor indications. For more information, please visit the company website at www.aprea.com.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended related to our study analyses, clinical trials, regulatory submissions, and projected cash position. We may, in some cases use terms such as "future," "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "targeting," "confidence," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team and on information currently available to management that involve risks, potential changes in circumstances, assumptions, and uncertainties. All statements contained in this press release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize, and achieve market acceptance of our current and planned products and services, our research and development efforts, including timing considerations and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including, without limitation, risks related to the success, timing, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses, presentations at conferences and data reported in an abstract, and receipt of interim or preliminary results (including, without limitation, any preclinical results or data), which are not necessarily indicative of the final results of our ongoing clinical trials, our understanding of product candidates mechanisms of action and interpretation of preclinical and early clinical results from its clinical development programs, and our ability to predict clinical outcomes based on such preclinical and early clinical results, our ability to continue as a going concern, and the other risks, uncertainties, and other factors described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the U.S. Securities and Exchange Commission. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to update such forward-looking statements for any reason, except as required by law.

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